510(k) Summary

AUG 24 2007

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 9807.92.

The Assigned 510(k) Number is: K072210

1. Applicant Device Information

Device Trade/Proprietary Name: CHISON 8300 Digital Ultrasonic Diagnostic Imaging System
Device Common Name: Ultrasonic Imaging System and Transducers
Device Classification Name: Ultrasonic Pulsed echo Imaging System
& Diagnostic Ultrasonic Transducer
Review Category: Tier II
Product Code: IYO and ITX
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Device Class: II
Prescription Status: Prescription Device
Establishment Registration Number: 3004753388
Owner/operator Number: 9066279
Intended Use:
CHISON 8300 is a portable digital ultrasonic diagnostic B/W system applied in ultrasound diagnostic examination of abdomen, obstetric, gynecology, urology, cardiology and small parts etc. This device is intended to adult, pregnant woman, pediatrics.

Submitter Information
Manufacturer Name:
CHISON MEDICAL IMAGING CO., LTD.
No.8 Xiangnan Road, Shuofang, New District,
Wuxi, China 214142
Establishment Registration Number: 3004753388
Owner/operator Number: 9066279

Contact Person of the Submission:
Ms. Ruoli Mo; Ms. Karen Xie

Display mode: B, B/B, 4B, B/M, M. In the B or M mode, 128 frames of real-time image can be stored in Cine-memory.

The Standard configuration of the applicant device includes Main unit, probes, relative accessories, please see the **Figure IV-1 ~ Figure IV-6** in **Chapter IV Device Description** for the pictures of the device.

There's no unique feature or technological characteristics for the applicant device.

The accessories are listed as following tables:

Part Name	Model	Application
Video Printer	SONY or Mitsubishi video printer	Print video image
Trolley	TR-8000	Carry 8300 and its accessories

The Applicant Probe type:

Probe Model	Type	Frequency	Application	Track
C60613S	Convex	3.5 MHz	Abdomen Probe	1
L40617S	Liner Probe	7.5 MHz	Superficial Probe	1
C12616S	Micro-convex	6.0 MHz	Transvaginal Probe	1

5. Effectiveness and Safety Considerations

Effectiveness:

Accuracy Test was conducted for the effectiveness:

The following Table 1, Table 2 and Table 3 display the measurement accuracy of different type transducers using with CHISON 8300.

Table 1 Measurement accuracy of CHISON-C60613S at 3.5MHz

Measurement	Unit	Range of availability	Accuracy
Axial Distance	mm	Full Screen (30~240mm)	<±5%
Lateral Distance	mm	Full Screen (0~240mm)	<±5%
Circumference: tracing method elliptical method	mm	Full Screen (0~240mm)	<±5%
Area: tracing method elliptical method	cm^2	Full Screen (0~240mm)	<±10%
Heart Rate	bpm	15~999	<±5%

Table 2 Measurement accuracy of CHISON-C12616S at 6.0MHz

Measurement	Unit	Range of availability	Accuracy
Axial Distance	mm	Full Screen (40~150mm)	<±5%
Lateral Distance	mm	Full Screen (0~150mm)	<±5%
Circumference: tracing method elliptical method	mm	Full Screen (0~150mm)	<±5%
Area: tracing method elliptical method	cm^2	Full Screen (0~150mm)	<±10%

Table 3 Measurement accuracy of CHISON-L40617S at 7.5 MHz

Measurement	Unit	Range of availability	Accuracy
Axial Distance	mm	Full Screen (3~100mm)	<±5%
Lateral Distance	mm	Full Screen (0~100mm)	<±5%
Circumference: tracing method elliptical method	mm	Full Screen (0~100mm)	<±5%
Area: tracing method elliptical method	cm^2	Full Screen (0~100mm)	<±10%

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Safety Considerations:

The Electrical Safety Testing following IEC 60601-1 and Electromagnetic Compatibility Testing following IEC 60601-1-2 was conducted as the Test Report No. 48889604302.
Please see the Appendix II for the test report.

For invasive probe, the means to limit the surface heating of the transvaginal probe is provided.

Conclusion: The applicant device is safe with regards to electrical safety and electromagnetic compatibility.

Per 1987 Tripartite Biocompatibility Guidance to Medical Device, FDA Guideline "INFORMATION FOR MANUFACTURERS SEEKING MARKETING CLEARANCE OF DIAGNOSTIC ULTRASOUND SYSTEMS AND TRANSDUERS" dated May 1, 1997 and with regard to Table 1 Initial Evaluation Tests for Consideration and Table 2 Supplementary Evaluation Tests for Consideration in ISO 10993-1:2003(E), Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing, the necessary tests for Biocompatibility Testing includes: Cytotoxicity, Sensitization, Irritation or Intracutaneous Reactivity.

The biocompatibility test results of all kinds of material of finished products are provided in **Chapter IV, Section 4.3 Biological Specifications** and **Appendix I.**

Conclusion: The all conducted Biological Evaluation Tests are in compliance with the standards of ISO 10993, "Biological Evaluation of Medical Devices". The compatibility of all the possible skin-contact component material in the finished product meets the requirement of Biocompatibility

The applicant device is **Substantially Equivalent (SE)** to the predicate device which is US legally market device. Therefore, the applicant device is determined as safe and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Chison Medical Imaging Co., Ltd.
c/o Mr. Tamas Borsai
Division Manager, Medical Division
TUV Rheinland of North America
12 Commerce Road
NEWTOWN CT 06470

AUG 2 4 2007

Re: K072210
Trade/Device Name: CHISON 8300
Regulation Number: 21 CFR §892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, ITX
Dated: June 23, 2007
Received: August 9, 2007

Dear Mr. Borsai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the CHISON 8300, as described in your premarket notification:

Transducer Model Number

CHISON L40617S	CHISON C60613S	CHISON C12616S

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may

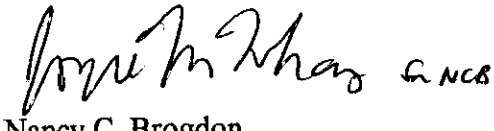
publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Andrew Kang, M.D. at (240) 276-3666.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

K072210

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Device Name: CHISON 8300

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (B/M)	Other (specify)
Ophthalmic										
Fetal		N	N						N	
Abdominal		N	N						N	
Intraoperative (specify)										
Intraoperative Neurologica										
Pediatric		N	N						N	
Small Organ (specify)		N	N						N	
Neonatal Cephalic										
Adult Cephalic										
Cardiac		N	N						N	
Transesophageal										
Transrectal										
Transvaginal		N	N						N	
Transurethral										
Intravascular										
Peripheral Vascular		N	N						N	
Laparoscopic										
Musculo-skeletalConventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Comments:

Small organs include: thyroid, parathyroid, parotid, submaxillary gland, and Breast

Pediatric Intended Uses include: Cardiology, Abdomen, Peripheral Vasa

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K072210

✓ Prescription Use (Per 21 CFR 801.109)

K072210

Diagnostic Ultrasound System Indications for Use Form

Device Name: CHISON L40617S

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (B/M)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative(specify)										
Intraoperative Neurological										
Pediatric(specify)		N	N						N	
Small Organ(specify)		N	N						N	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethra										
Intravascular										
Peripheral Vascular		N	N						N	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other(specify)										

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✓ Prescription Use (Per 21 CFR 801.109

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K072210

K072210

Diagnostic Ultrasound System Indications for Use Form

Device Name: CHISON C60613S

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (B/M)	Other (specify)
Ophthalmic										
Fetal		N	N						N	
Abdominal		N	N						N	
Intraoperative(specify)										
Intraoperative Neurological										
Pediatric(specify)										
Small Organ(specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		N	N						N	
Transesophageal										
Transrectal										
Transvaginal										
Transurethra										
'ravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other(specify)										

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510(k) Number K072210

K072210

Diagnostic Ultrasound System Indications for Use Form

Device Name: CHISON C12616S

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (B/M)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative(specify)										
Intraoperative Neurological										
Pediatric(specify)										
Small Organ(specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal		N	N						N	
Transurethra										
Transvascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other(specify)										

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